

REMARKS

Status

Claims 1, 10-12, 14 and 22-24 were pending in this Office Action. The present response does not add or cancel any claims. Accordingly, it is now claims 1, 10-12, 14 and 22-24, as amended, which are at issue.

The Office Action

In the Office Action mailed August 16, 2007, claims 1, 10-12, 14 and 22-24, all claims then at issue, were rejected. Claims 1, 10-12, 14 and 22-24 were rejected under 35 U.S.C. §112, first paragraph. Additionally, claims 1, 14, 22 and 24 were rejected under 35 U.S.C. §112, second paragraph.

Claims 1, 10-12, 14 and 22-24 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent 6,172,114 of McCabe in view of U.S. Patent 5,968,900 of Greenhaff, and further in view of U.S. Patent 6,200,569 of Cheng and U.S. Patent 6,051,236 of Portman.

Applicant thanks the Examiner for the search and for the Office Action, and for the thorough explanation of the basis of the rejections.

The Present Invention

In order to better differentiate the invention, as presently claimed, over the prior art of record, Applicant will briefly recapitulate the features of this invention.

The present invention is directed to a dietary supplement which enhances the uptake of creatine in muscles and hence is useful for increasing lean muscle mass. The present invention is based upon the finding that cinnamon-derived materials, and in particular a water-soluble extract of cinnamon, when taken together with creatine monohydrate and/or a creatine magnesium chelate, significantly enhances the uptake of creatine by muscle tissue. As detailed in the

pending application, for example at the paragraph bridging pages 9 and 10, it is stated that the composition of the present invention causes a 10 to 40 percent increase in creatine content of muscle as measured by tissue biopsy. This synergistic interaction of creatine and water-soluble cinnamon extract is nowhere shown or suggested in the prior art and is the basis of the presently claimed invention. As further detailed in the specification, for example at page 10, this increase in creatine uptake by muscles translates to an increase in muscle strength and such increase has directly been correlated with use of the composition of the present invention.

In summary, the present invention, as now set forth in the claims, is directed to a dietary supplement which consists essentially of a particular water-soluble extract of cinnamon and a particular grouping of creatine compounds. The composition may optionally include a carbohydrate. As is specifically detailed in the claims, these materials interact synergistically to enhance the uptake of creatine by muscles, and the specification presents data substantiating the operation and efficacy of the claimed composition. As will be explained in detail hereinbelow, the operation of the water-soluble cinnamon extract to enhance creatine uptake is nowhere shown or suggested in the prior art, and the claimed subject matter is patentable.

The Rejections under 35 U.S.C. §112, First Paragraph

Claims 1, 10-12, 14 and 22-24 were rejected under 35 U.S.C. §112, first paragraph, as failing to be fully supported by the specification as originally filed. As stated in the second full paragraph on page 3 of the Office Action, it is the Examiner's opinion that claims then pending were broadly drawn to cinnamon, extract of cinnamon, or derivative thereof, and it was the Examiner's opinion that this language was not fully supported in the specification, and consequently the invention could not be practiced without undue experimentation.

Applicant respectfully submits claims then pending were limited to a composition consistent essentially of: a first ingredient which is restricted to a water-soluble extract of cinnamon, and a second ingredient which is creatine monohydrate and/or a creatine magnesium chelate. As such, Applicant was not intending to claim compositions based upon a cinnamon component which is other than a water-soluble extract of cinnamon. However, there may have been some ambiguity in the claims since paragraph c of claim 1, in the whereby clause, included the broad language referred to by the Examiner. Applicant apologizes for any ambiguity resultant from this language and has by the present amendment further clarified claim 1.

As claim 1 now stands, it unambiguously recites that the composition of the present invention is based upon "a water-soluble extract of cinnamon." All reference to cinnamon and cinnamon derivatives has been stricken. The application as originally filed presented extensive teaching regarding the preparation and use of a water-soluble extract of cinnamon, and in that regard the specification further refers to the fact that such extracts are commercially available. In view of all of the foregoing, Applicant respectfully submits that one of skill in the art could, with reference to the specification, readily prepare and use the compositions of the present invention for the purpose of enhancing creatine uptake by muscle. Furthermore, as detailed in the specification, the efficacy of the composition in enhancing creatine uptake and subsequently building muscle strength has been demonstrated. Therefore, the subject matter of all pending claims is now fully enabled in the specification as originally filed, and any rejections under 35 U.S.C. §112, first paragraph, are overcome. Reconsideration and withdrawal of these rejections is respectfully requested.

The Rejections under 35 U.S.C. §112, Second Paragraph

A number of claims were rejected under 35 U.S.C. §112, second paragraph, on particular grounds noted by the Examiner.

Claim 1 was subject to a first rejection on the grounds that the limitation "said cinnamon, extract of cinnamon or derivative thereof" in lines 6 and 7 does not have a sufficient antecedent basis in the claim. By the present amendment, as discussed above, this error has been corrected and the rejection is overcome.

Claim 1 was further rejected on the grounds that the limitation "the muscle" in line 7 does not have a sufficient antecedent basis. By the present amendment to claim 1, this error has been corrected.

Claim 1 was further rejected on the grounds that the recitation of "a water-soluble extract of cinnamon and creatine monohydrate" is unclear with regard as to whether Applicant is claiming an extract of cinnamon and an extract of creatine monohydrate or an extract of cinnamon and further claiming the use of creatine monohydrate. Applicant apologizes for any uncertainty in the claim. Applicant's intention was to claim a composition which consisted essentially of (a) a water-soluble extract of cinnamon and (b) creatine monohydrate and/or a creatine magnesium chelate. The subparagraph structure of the claim was selected to support this interpretation. In order to further the claim, Applicant has further amended claim 1 to recite that component (a) is "a first ingredient consisting essentially of" the water-soluble extract of cinnamon and component (b) is "a second ingredient consisting essentially of" the creatine material. As such, the claim now makes very clear that the two components set forth in subparagraphs a and b are distinct ingredients. Applicant respectfully submits that in view of this amendment, the Examiner's final objection to claim 1 is overcome.

Claim 14 was objected to on the grounds that the recitation of "said supplement" in line 2 thereof lacks an antecedent basis. By the present amendment, the claim has been amended to recite "said dietary supplement" which finds a full antecedent basis in the first line of claim 14.

Claim 14 was further objected on the grounds that the recitation of "56 mmol/kd dry muscle" was unclear. Applicant respectfully submits that this term included a typographical error, and by the present amendment has replaced "kd" with the accepted and correct terminology "kg" referring to kilograms. Accordingly, this objection is overcome.

The Examiner further stated that it is unclear if claim 14 is intended to be a method claim since it is alleged to include method steps. Applicant states for the record that claim 14 is a product claim further characterizing the dietary supplement in terms of its biological activity. In that regard, the claim of necessity includes parameters detailing a treatment regimen and results achieved thereby. These details are essential for establishing the biological activity which is the basis for characterizing the composition which is the actual subject of this claim.

Claim 22 was objected to on the grounds that there is insufficient antecedent basis for the term "that fraction of cinnamon". By the present amendment, "that" has been replaced by "a" thereby overcoming this rejection.

In a second rejection of claim 22, the Examiner held that the recitation "comprised of that fraction of cinnamon" is unclear. Applicant respectfully submits that claim 22 further characterizes the water-soluble extract of cinnamon as being further soluble in 0.1 N acetic acid. As detailed in the specification, water-soluble cinnamon extracts can be prepared by an extraction process using water which has been mildly acidified as for example with acetic acid. As such, claim 22 is directed to that subset of water-soluble extracts of cinnamon prepared by use of an acidified solution.

Claim 24 was objected to on the grounds that the recitation of "supplement" in lines 2 and 3 is unclear as to whether it is referring to the claimed dietary supplement or to some other material. By the present amendment, Applicant has made clear that this language is referring to the dietary supplement which is the subject of the claim.

In view of the foregoing, Applicant respectfully submits that all rejections under 35 U.S.C. §112, second paragraph, are overcome. Reconsideration and withdrawal thereof is respectfully requested.

The Rejections under 35 U.S.C. §103

Claims 1, 10-12, 14 and 22-24 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent 6,172,114 of McCabe taken in view of the combination of U.S. Patents 5,968,900 of Greenhaff; 6,200,569 of Cheng and 6,051,236 of Portman.

In making this rejection, the Examiner cited the McCabe patent for its teaching of compositions of creatine and carbohydrates as used for increasing body mass, strength and energy and for reducing body fats. The Examiner acknowledges on the record that the McCabe patent does not recognize the use of any water-soluble extract of cinnamon in combination with creatine and carbohydrates, and the Examiner further acknowledges that specific carbohydrates and dosage levels claimed in the present application are not present in McCabe.

The Examiner cited to the Greenhaff patent for its teaching of a dietary supplement comprising creatine and carbohydrate and for the further teaching that increasing the amount of creatine within a muscle favorably affects muscular performance. The Examiner further notes that athletes additionally desire to enhance glycogen levels in muscles in order to enhance muscular performance, but the Examiner does not tie this role of glycogen in any way to the presence of creatine in muscles.

The Cheng patent was cited for its teaching of water-soluble cinnamon extracts and further specific activity as insulin potentiating agents effective to lower blood glucose.

A fourth reference cited in formulating this rejection is the Portman patent which teaches a nutritional composition based upon carbohydrates. As an aside, the Portman patent teaches that the carbohydrate composition may be flavored with various agents which include extracts of apple, banana, cherry, cinnamon, cranberry, grape, honeydew, honey, kiwi, lemon, lime, orange, peach, peppermint, pineapple, raspberry, tangerine, watermelon, wild cherry and various equivalents. There is no teaching whatsoever in Portman of any active role for a cinnamon flavoring with regard to affecting carbohydrate metabolism, or uptake of any biologically active material. Furthermore, there is no teaching in Portman of the specific water-soluble extract used in the present invention.

The prior art does not provide a sound basis for the rejection of the pending claims. The Cheng patent provides the only teaching regarding the water-soluble cinnamon extract set forth in the claims, and this patent is in no way concerned with materials or methods for building muscle mass and does recognize that the cinnamon extract can act to increase the uptake of creatine by muscles from a creatine-containing composition. The only other prior art reference which even discusses cinnamon at all is the Portman patent, and this patent utilizes cinnamon as a flavoring agent in a high carbohydrate nutritional supplement. While the Portman patent is directed to compositions for use in connection with strength training, it nowhere discusses the role of creatine or any interaction between creatine and the claimed water-soluble cinnamon extract. The remaining patents of McCabe and Greenhaff are all directed to compositions containing creatine and carbohydrates and as such represent prior art superseded by the presently claimed compositions.

At the very best, the prior art of record shows separate compositions which include a water-soluble cinnamon extract, creatine, and carbohydrates. There is no teaching which would lead one of skill in the art to include a water-soluble cinnamon extract in a creatine-based composition for the purpose of promoting creatine uptake and increasing a user's strength. The prior art teaching regarding the role of water-soluble cinnamon extract is with regard to its properties in modulating abnormal blood sugar levels; hence, one of skill in the art would not expect that this water-soluble cinnamon extract of the type shown in Cheng would be operative to increase creatine uptake. Hence the prior art cannot begin to suggest or make obvious the claimed composition.

However, for the sake of argument, even if it could be established that the Examiner has presented a *prima facie* case of obviousness of the composition, as a matter of law, this position is rebuttable and confirms the patentability of these claims.

The courts have long recognized that unexpected results are an indicator of nonobviousness (see for example *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995) "One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of unexpected results, i.e., show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected."). In the present case, Applicant has demonstrated in the specification that the water-soluble cinnamon extract interacts synergistically with the creatine-based material to enhance the uptake of creatine by 10-40 percent in muscle tissue, and this benefit results in an increase in muscular strength. The prior art nowhere shows or suggests any such beneficial, synergistic interaction, and in view of these unexpected results, Applicant respectfully submits

that the presently claimed invention is nonobvious. Reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

The Specification

In the Office Action, the Examiner noted that the trademark "Cinnulin PF" has been used in this application, and the Examiner has directed the Applicant to assure that this trademark is properly used and identified. By the present response, Applicant has amended the specification to indicate that the mark "Cinnulin PF" is in fact registered to Integrity Nutraceuticals International.

Conclusion

By the present response Applicant has addressed all issues raised by the Examiner. The application is now in condition for allowance. Any questions, comments or suggestions which the Examiner may have, which will place the application in still better condition for allowance, should be directed to the undersigned attorney.

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Respectfully submitted,

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